

DECLARATION OF CONFORMITY
EU MDR 2017/745

Manufacturer (EU MDR 2017/745):

QUALITEAM s.r.l.

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Single Registration Number (SRN): TO-1026079

Qualiteam s.r.l., as the legal manufacturer, hereby declares under its sole responsibility that the medical device described below complies with the applicable requirements of Regulation (EU) 2017/745 on medical devices..

Product identification

Product name: AxillaPad perspiration pads

Basic UDI-DI: 803367519QBAXF7

GMDN code: 41058 AxillaPads

Product REF and UDI-DI (EAN-13):

QBAX Adult (UDI-DI 8033675192048)

QBPAx Pediatric (UDI-DI 8033675192338)

QBITAX Infant Toddler (UDI-DI 8033675190662)

Intended purpose:

AxillaPads may provide increased comfort under the armpits when chest support products such as QualiBreath, QualiBra Advanced and the Thor products in situations where patients feel the upper border of said products cause discomfort. AxillaPads also helps protecting the chest supports from excessive perspiration to avoid over-washing whereby the lifetime of the products can be prolonged.

Risk class:

The device is classified as Class I according to EU MDR 2017/745, Annex VIII, Rule 1 (non-invasive, non-sterile, non-measuring).

Conformity statement:

The device conforms to the General Safety and Performance Requirements (GSPRs) of Annex I of Regulation (EU) 2017/745, as demonstrated in the Technical Documentation maintained at the manufacturer's address.

The Technical Documentation will be retained for at least 10 years after the last device has been placed on the market.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Burolo, November 15, 2025.

Joachim Hansen

President & CEO

Qualiteam s.r.l.

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